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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,020	11/27/2001	Mazen H. Hanna	0108.11	3104

21968 7590 05/20/2004

NEKTAR THERAPEUTICS  
150 INDUSTRIAL ROAD  
SAN CARLOS, CA 94070

EXAMINER
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JOHNSON, EDWARD M

ART UNIT	PAPER NUMBER
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1754

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/996,020	<b>Applicant(s)</b> HANNA ET AL.	
	<b>Examiner</b> Edward M. Johnson	<b>Art Unit</b> 1754	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 February 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 30-123 is/are pending in the application.
- 4a) Of the above claim(s) 30-44 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 45-56 is/are allowed.
- 6) ☒ Claim(s) 57-63, 70-80, 83-86, 90-109 and 113-123 is/are rejected.
- 7) ☒ Claim(s) 64-69, 81, 82, 87-89 and 110-112 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 57-63, 70-80, 83-86, 90-109, and 113 are rejected under 35 U.S.C. 102(b) as being anticipated by Inoue et al. US 4,514,574.

Regarding claims 57, 90, 100, and 107, Inoue '574 discloses supercritical gas extraction of isomers with carbon dioxide solvent (see abstract, Examples).

Regarding claims 58-63, 70-80, 83-86, 91-99, 101-106, 108-109, and 113, Inoue '574 discloses two isomers, a solvent comprising carbon dioxide and polar solvents, contacting at the claimed conditions (see abstract, Examples, and column 2, lines 11-21).

3. Claims 57-63, 70-80, 83-86, 90-109, and 113 are rejected under 35 U.S.C. 102(b) as being anticipated by Sebastian US 5,196,575.

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Regarding claims 57, 90, 100, and 107, Sebastian '575 discloses supercritical separation of isomers comprising flowing supercritical carbon dioxide/polar solvent mixture, contacting the isomers, and precipitating (see column 2, lines 15-35).

Regarding claims 58-63, 70-80, 83-86, 91-99, 101-106, 108-109, and 113, Sebastian '575 discloses two isomers and carbon dioxide/polar solvent solution with the claimed method steps and particular conditions (see column 2, lines 27-20, abstract, and Examples).

4. Claims 57-63, 70-80, 83-86, and 90-106 rejected under 35 U.S.C. 102(b) as being anticipated by Murthy et al. US 4,737,384.

Regarding claims 57, 90, and 100, Murthy '384 discloses depositing a coating onto a substrate comprising exposing a substrate at supercritical temperatures and pressures to a solution (see column 2, lines 11-24).

Regarding claims 58, 60-62, 70-79, 84-86, 95-99, and 102-106, Murthy '384 discloses a solution at supercritical temperatures and pressures (see column 2, line 16) and carbon dioxide and other solvents (see column 4, line 11).

Regarding claim 59, Murthy '384 discloses insoluble material dispersed in the solvent undissolved (see column 5, lines 1-15).

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Regarding claims 63, 80, 83, 91-94, 101 Murthy '384 discloses exposing a substrate that is already present to a solution (see column 2, lines 15-17).

5. Claims 57-63, 70-80, and 90-106 rejected under 35 U.S.C. 102(b) as being anticipated by Cole et al. US 5,066,522.

Regarding claims 57, 90, and 100, Cole '522 discloses coating a substrate by admixing with a supercritical fluid and precursor adhesive composition (see abstract).

Regarding claims 58-63, 70-80, 83-86, 91-99, 101-106 Cole '522 discloses mixing a supercritical fluid, which contains water (abstract), dispersion (see Figures and column 3, lines 10-13), carbon dioxide (see column 1, lines 18-25).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 114-123 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Inoue '574.

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Regarding claims 114-123, Inoue '574 discloses supercritical gas extraction of isomers (see abstract, Examples).

8. Claims 114-123 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over anticipated Sebastian '575.

Regarding claims 114-123, Sebastian '575 discloses supercritical separation of isomers comprising flowing supercritical carbon dioxide/polar solvent mixture, contacting the isomers, and precipitating (see column 2, lines 15-35).

9. Claims 114-123 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over anticipated Murthy '384.

Regarding claims 114-123, Murthy '384 discloses depositing a coating onto a substrate comprising exposing a substrate at supercritical temperatures and pressures to a solution (see column 2, lines 11-24).

10. Claims 114-123 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cole '522.

Regarding claims 114-123, Cole '522 discloses coating a substrate by admixing with a supercritical fluid and precursor adhesive composition (see abstract).

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11. In the event any differences can be shown for the product of the product-by-process claims 114-123, as opposed to the product taught by Inoue, Sebastian, Murthy, and/or Cole, such differences would have been obvious to one of ordinary skill in the art at the time the invention was made as a routine modification of the product in the absence of a showing of unexpected results; see also *In re Thorpe*, 227 USPQ 964 (Fed.Cir. 1985).

***Allowable Subject Matter***

12. Claims 45-56 are allowed.

13. Claims 64-69, 81-82, 87-89, 110-112 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. The following is a statement of reasons for the indication of allowable subject matter: It would not have been obvious to one of ordinary skill in the art at the time the invention was made to: 1. enter both flows at the same location and simultaneously extract the vehicle from the substance at the location in the method of the instant claim 45; 2. flow the supercritical fluid using the coaxial nozzle with passages that terminate adjacent to one another in the method of the instant claims 64-65 and 110-111; 3. use the 0.001-0.2 ratio of

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solution/suspension to supercritical fluid in the method of the instant claims 81 and 112; 4. use less than about 30% of first vehicle in the method of the instant claim 82; 5. use a seed of insoluble material in the second vehicle to induce nucleation upon contact in the method of the instant claim 87; nor 6. switch between two or more particle formation vessels or collecting means in the method of the instant claim 89.

***Response to Arguments***

15. Applicant's arguments filed 2/25/04 have been fully considered but they are not persuasive.

It is argued that claim 57 and its dependents... surrounded by a coating layer. This is not persuasive because Inoue discloses contacting the material with a supercritical fluid, which would inherently surround the material, and which is Applicant's only claimed process step. It is noted that Applicant's cited claim limitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).



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It is argued that claim 107 and its dependents... particle formation vessel. This is not persuasive because Applicant appears to admit that the fluid is "passed over" the bulk mixture, which would anticipate the claimed co-introduction and also because Inoue discloses contacting the material and fluid before separation, which separation would inherently require that the fluid and material be introduced together.

It is argued that Sebastian's is a process for *extracting*... one of those components. This is not persuasive because Sebastian discloses flowing supercritical carbon dioxide/polar solvent mixture and contacting the isomer compounds with the fluid and precipitating, which anticipates Applicant's claimed process step. Contrary to Applicant's apparent suggestion, the disclosed precipitation would form particles. It is also noted that Applicant's cited claim limitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

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It is argued that Murthy's coating process is very different to that of the present invention. This is not persuasive because Applicant does not claim a "separate" SCF as an anti-solvent. It is noted that the features upon which applicant relies (i.e., a "separate" SCF as anti-solvent) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, and contrary to Applicant's assertion, Murthy discloses coating a substrate (see column 2, lines 11-14).

It is argued that Cole teaches a process... coating layer. This is not persuasive because Applicant does not claim a process for making a coating that is not a liquid. It is noted that the features upon which applicant relies (i.e., a coating in a particular state that is not a liquid) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

It is argued that the present invention involves a very specific... fluid co-introduction. This is not persuasive for the reasons above.

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It is argued that none of the cited art addresses the problem... pharmaceutical formulations. This is not persuasive for the reasons above and also because Applicant does not claim a pharmaceutical intended use, which, even if claimed, would not be given undue patentable weight. It is noted that the features upon which applicant relies (i.e., a pharmaceutical intended use) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

It is argued that the present invention provides a *single* step... this is not persuasive because Applicant claims a process using the open language "comprising", which does not exclude prior art that teaches additional steps, so long as the claimed process step is disclosed.

#### **Conclusion**

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action

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is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward M. Johnson whose telephone number is 571-272-1352. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stanley S. Silverman can be reached on 571-272-1358. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-0987.

EMJ

  
STANLEY S. SILVERMAN  
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